

SJ Quinney College of Law, University of Utah Utah Law Digital Commons

Utah Law Faculty Scholarship

Utah Law Scholarship

2015

Risk Management and Conflicts of Interest

Leslie P. Francis

S.J. Quinney College of Law, University of Utah, leslie.francis@law.utah.edu

Follow this and additional works at: <https://dc.law.utah.edu/scholarship>

Part of the [Health Law and Policy Commons](#)

Recommended Citation

Francis, Leslie P., "Risk Management and Conflicts of Interest" (2015). *Utah Law Faculty Scholarship*. 151.
<https://dc.law.utah.edu/scholarship/151>

This Book Chapter is brought to you for free and open access by the Utah Law Scholarship at Utah Law Digital Commons. It has been accepted for inclusion in Utah Law Faculty Scholarship by an authorized administrator of Utah Law Digital Commons. For more information, please contact valeri.craigle@law.utah.edu.

Chapter 4

Risk Management and Conflicts of Interest

Leslie Francis

Abstract

Risk management aims to reduce the costs of adverse events. In entities such as hospitals, risk managers do this in two ways: reducing the likelihood or seriousness of adverse events and reducing the costs of these events when they do happen. Activities aimed at the latter present direct conflicts of interest between protecting the institution and respecting the interests of the clients served by the institution—so-called institutional conflicts of interest. Activities aimed at the former would appear to benefit all parties--those at risk of accidents (because the risk is reduced) and the institution (because reducing risks also reduces the costs of adverse events)--and thus escape problems of conflicts. This appearance may also be misleading, however, if efforts to reduce risks to agents of the institution (such as hospital staff) conflict indirectly with efforts to reduce risks to clients (such as patients). Here, too, institutional conflicts of interest may arise for the risk manager.

This chapter discusses the role of the risk manager in handling institutional conflicts of interest in health care organizations. When risk managers attempt to reduce the costs of adverse events to the institution, conflicts of interest are likely to arise and to present ethical issues for the risk manager. These conflicts are institutional ones that are built into the risk manager's role: the risk manager's goal is to settle potentially expensive claims on terms that are favorable to the institution rather than on the terms that might be most beneficial to the patient. These conflicts must be identified and managed ethically.

Introduction

In the play, "An Enemy of the People," Ibsen's character Dr. Thomas Stockmann informs local officials that their town's well-known and highly lucrative baths are contaminated by runoff from a local tannery. Stockmann is the chief medical officer for the baths, much sought after for their healing capabilities. After observing unusual episodes of illness in some of the baths' visitors, Stockmann sends water samples off for analysis to a major university. When the results indicate contamination, he urges closure of the baths to protect the health of visitors—a judgment based on his assessment of the risks and benefits of leaving the baths open.

Ibsen's play is a classic drama of honesty and self-righteousness against community spirit and greed—with all the subtle strengths and weaknesses of each of these. But it is also a prescient drama about the role of a public health risk manager and the individual and social conflicts attending that role. As an individual, Stockmann prides himself on being a scientist and taking care to withhold his concerns from the community until he has confirmed test results. Yet there is also a ring of "I told you so"

in how he conveys the news to the town officials; Stockmann had argued for a more expensive piping system that would have avoided the risk of pollution contamination of the baths. Although Stockmann expects to be a town hero for what he has learned, it comes as no surprise to the audience that he is disbelieved, dismissed from his position, evicted from his home, and declared an “enemy of the people.”

In the play, Ibsen draws a masterful portrait of conflicts of interest: Stockmann has interests in his scientific reputation, his family, his position as medical director, and his medical practice. The town has financial interests in the success of the baths and in its reputation. The town leaders have interests in their positions with the town as well as their own economic interests. But there is more. At the end of the play, Stockmann is confronted with perhaps the most traditional form of conflict of interest: he learns that the owner of the tannery, his wife’s adoptive father, was planning to leave a sizeable inheritance to Stockmann’s wife and children. To pressure Stockmann to clear the tannery of responsibility for the pollution, his adoptive father-in-law has invested his fortune in the baths and tells Stockmann that unless the baths are cleared, he will leave the fortune to a charity. Deprived of income with which to support his family, Stockmann faces a “horribly painful dilemma,” deepened by the recognition that some believe that he has criticized the baths so that his adoptive father in law could profiteer from investing in the baths on highly favorable terms. Yet Stockmann remains pure: he refuses the inheritance and plans to provide medical care for the poor in the town. Ibsen’s play was written over one hundred years ago, but healthcare risk managers face many of these same conflicts of interest today.

This chapter begins with a discussion of conflicts of interest, both individual and institutional. It then considers the role of the healthcare risk manager and explains how that role may incorporate institutional conflicts of interest. The chapter then applies this analysis to the role of the risk manager in disclosure or apology programs designed to reduce malpractice costs. It concludes with three suggestions for alleviating these conflicts of interest: limitations on confidentiality requirements in settlement agreements, a requirement that patients receive independent advice before entering these agreements, and development of the capability for independent review of settlements.

Understanding Conflicts of Interest

Understood most broadly, conflicts of interest in the professional context occur when judgments about the exercise of professional obligations are, or might be, affected unduly by interests extrinsic to professional relationships. One influential characterization of this situation is that “secondary” interests adversely affect “primary” professional interests. (Thompson 1993) Identifying such conflicts thus requires a determination of professional obligations as primary interests, an understanding of what interests are extrinsic to the professional relationship and thus secondary, and judgments about when such secondary interests affect or might affect professionals in ways they should not.

Some professions such as law have developed highly formalized statements of professional obligations and how various conflicts of interest may affect them; disciplinary mechanisms may be invoked when actions violate these obligations. Other professions have far less elaborate professional codes. Unlike law or medicine, many professions—including healthcare risk management in most states—do not require

licensure—a common method for the enforcement of professional obligations. In many fields, moreover, contractual obligations to employers such as confidentiality, non-compete clauses, or agreements to limit services, may lie in uneasy tension with primary profession obligations or other secondary interests.

As will be discussed more fully below, there may also be no clear delineation of which interests are considered secondary to the professional relationship. Personal financial interests and interests of family members are standardly identified as such interests. (Lo & Fried 2009, p. 32) General ideological orientations or political affiliations are frequently not judged to be conflictual interests, even though they may affect decision-making, unless they can be linked directly to some form of personal advantage. Interests in reputation, public recognition, or career advancement may be as influential on decision-making but far more difficult to identify than financial interests. (Thompson 1993) They thus may be considered secondary interests although they are often not addressed directly in professional codes of conduct or conflicts of interest policies.

Secondary interests are not problematic per se. They may become problematic when they divert judgment in the context of professional relationships. Thompson (1993) writes:

The secondary interest is usually not illegitimate in itself, and indeed it may even be a necessary and desirable part of professional practice. Only its relative weight in professional decisions is problematic. The aim is not to eliminate or necessarily to reduce financial gain or other secondary interests (such as preference for family and friends or the desire for prestige and power). It is rather to prevent these secondary factors from dominating or appearing to dominate the relevant primary interest in the making of professional decisions.

In healthcare, observational research has addressed correlations between individual economic interests of physicians and treatment recommendations. (Lo & Fried 2009, Ch. 6) Such research also reveals correlations between relationships with pharmaceutical companies and other commercial enterprises and published research findings. (Lo & Fried 2009, Ch. 4) When the interests of patients or human subjects are compromised, the influence of conflicts of interest is clearly problematic. A well-known illustration is the death of Jesse Gelsinger, a participant who died in a trial of gene therapy at the University of Pennsylvania. The study's lead researcher had substantial financial interests in the company that would profit if the trials were successful—interests that were valued at least \$13.5 million and perhaps much more. (Wilson 2010) The University also had equity interests in the company and financial interests in continuing to receive research support from the company. Indeed, the researcher was permitted to have such large financial interests in an agreement that supposedly shielded him from making scientific decisions and provided the University with the relationship with the company. Neither Jesse Gelsinger nor his family were informed of the extent of the financial ties or of potential risks of the study that had become apparent in earlier trials using animals as well as with earlier patients in the study. (Wilson 2010) The firestorm of criticism that followed Gelsinger's death in the trial focused primarily on these financial

ties—but reputational, career, and institutional interests may also have played important roles in the tragedy, so much so that Wilson (2010) argues that prohibition of the financial ties might not have been all that was necessary.

Discussions of conflicts of interest in healthcare increasingly recognize that institutional conflicts may exist in addition to individual conflicts (Rose 2013, Friedman & McKinney 2013, Lo & Field 2009; Emanuel & Steiner 1995) According to the Institute of Medicine, “Institutional conflicts of interest arise when an institution’s own interests or those of its senior officials pose risks of undue influence on decisions involving the institution’s primary interests” in the sense of obligations to those the institution serves (Lo & Field, 218) Federal regulations regarding government ethics also recognize the reality of institutional conflicts of interest; government employees, even special government employees such as those serving on advisory committees or temporary employees on leave from other positions, must not participate in the development of policies that might have a distinct impact on their institutions other than as members of a general class of institutions. (18 C.F.R. § 2640.203 (2014)) The examples in these regulations cite financial concerns, such as the development of a grants and contracts policy. Federal regulations governing conflicts of interest in federally funded research likewise focus on the financial interests of researchers or persons in institutional positions of authority. (42 C.F.R. Part 50, 45 C.F.R. Part 94 (2014); Friedman & McKinney 2013).

Particularly as federal funding for biomedical research has become more limited, academic medical institutions have pursued ties with industry. Concerns about maintaining the loyalty of commercial donors may impact decisions about faculty members and threaten the freedom to publish information critical of donors. (Shafer 2003) Competition to retain well-funded faculty members and to pursue grant opportunities has intensified as well. These are institutional—not individual—conflicts of interest and may require policies to address them (Friedman & McKinney 2013) or perhaps even restrict them. (Shafer 2003) Arguably, they may be as serious as individual conflicts of interest in diverting judgments away from the institution’s obligations to the individuals they serve. (Lo & Fried 2009, p. 216) However, regulations and institutional policies currently in place typically address institutional conflicts only as they are reflected in individual conflicts. There are some exceptions; for example, Stanford University’s institutional conflict of interest policy states explicitly that if investigators at the University are engaged in research that may affect the University’s intellectual property rights or equity holdings, these properties will be sequestered in an account held by an independent third party. (Stanford University 2014)

Conflict of interest rules seek to preserve the integrity of professional judgment and to maintain confidence in them. (Thompson 1993) Both individual and institutional conflicts of interest may result in a lack of trustworthiness and concomitantly inappropriately placed trust when those served by the institution do not realize that the institution’s interests are being placed first. (Rose 2013)

The Roles of Healthcare Risk Managers

Risk management in health care addresses the frequency, severity, and costs of adverse events. It is still a relatively new and still evolving professional field. Emerging in the

1970s in response to perceptions of a “malpractice crisis” of increased costs, the field originally sought to confront loss reduction directly by prevention and mitigation. (Core Risk Services 2014) The American Society for Healthcare Risk Management (ASHRM) was founded in 1980 as the American Society for Hospital Risk Managers and reflects these dual goals of increased safety and reduced institutional costs of errors or accidents.

One major way in which healthcare risk management is evolving as a field is its relation to and interconnection with quality improvement. For the most part, the fields have developed along separate paths and employ different goals and methods. If the goal of risk management is reduction of losses due to malpractice claims, and the goal of quality improvement is patient safety and care quality, the two are distinct enterprises each with unique ethical concerns. For example, the argument that it is appropriate to use patient data without consent for quality improvement activities as that might benefit their ongoing care or the care of patients like them cannot be applied as easily to the use of patient information to reduce liability costs. (Jennings et al. 2007, Baily et al. 2006) Data analyses devoted to patient safety may prioritize identifying events that may affect many people but that are unlikely to result in high-cost litigation, whereas analyses devoted to loss prevention may prioritize efforts to prevent events that give rise to such litigation. On the other hand, to the extent that improved patient safety and care quality reduce malpractice costs—as they surely do at least to some extent—the goals of the two fields align. Indeed, in many small healthcare facilities the same staff may perform both functions.

As concerns about patient safety and care quality have drawn increased attention, the need for connections between risk management and quality improvement activities has increasingly been emphasized. The publication of research about the frequency of medical errors (e.g. Leape 1994) highlighted problems of patient safety (IOM 1999) as well as the possibility that improved patient safety would reduce the costs of malpractice. The subsequent growth of the patient safety movement has led to recognition that risk management and care quality functions must work together. (ASHRM 2007) A primary example of the disclosure, apology, and offer programs described below, that of the University of Michigan, incorporates risk manager analysis of whether care was reasonable and how unreasonable forms of care can be avoided. The program assigns risk managers to particular clinical areas in order to carry out these patient safety activities. (Boothman et al. 2009) Such efforts of healthcare risk managers directed to reducing the frequency or severity of adverse events or to improving care quality would appear to be aligned with the interests of patients. To the extent that this alignment exists, interests of the healthcare facility and its patients are not in conflict.

In many other ways, however, interests of healthcare facilities and risk managers who work in them may be in conflict with the interests of patients. These conflicts and the ethical issues they create are the focus of the remainder of this chapter. The next section outlines the ethical principles that have been developed for public and private risk managers and considers how they might function in the context of conflicts of interest between institutions and the patients they serve. The chapter continues with an in depth discussion of an institutional conflict of interest that is arguably endemic in the role of the risk manager: development of disclosure, apology, and offer programs designed to encourage early settlements in situations in which patients were harmed by medical errors. A concluding section explores three possibilities for addressing this conflict:

limitations on confidentiality requirements in settlement agreements, a requirement that patients receive independent advice before entering these agreements, and development of the capability for independent review of settlements.

Ethics for Healthcare Risk Managers

The ASHRM Code of Professional Conduct (2012) divides risk manager responsibilities into two groups: responsibilities to the profession and responsibilities to those they serve. In the framework for conflict of interest analysis given above, these responsibilities would be the primary interests of the risk manager.

Among responsibilities to the profession, the ASHRM Code lists identifying, acknowledging, and disclosing potential conflicts of interest. Responsibilities to those served include respect by practicing in a non-discriminatory manner, recognizing that patients and their families are entitled to fair treatment, communicating honestly and factually, and sharing confidential information only where appropriate and permitted by law. This set of responsibilities also emphasizes patient safety; responsibilities of the risk manager include investigating and analyzing events to reduce the likelihood of similar injury to others, promoting cultural change that encourages reporting events that might result in injury, and advocating for patient safety.

In a third section, the ASHRM Code discusses individual conflicts of interest in further detail. This section singles out transactions with former employers or business associates, business transactions inuring to personal benefit or benefit of family members, and investments or activities which conflict or appear to conflict with the interests of employer or client as conflicts of interest for risk managers. The Code judges that business transactions inuring to personal benefit are unacceptable even with disclosure; other potential conflicts require full disclosure but may be permissible.

The ASHRM Code's treatment of conflicts of interest thus focuses on individual economic benefit or other individual benefits, not the possibility that the role of the risk manager may itself involve a conflict of interest between the interests of the healthcare institution and the interests of the patients it serves. For the risk manager, the primary professional interests of providing patients and their families with fair treatment and communicating factually and honestly could be deflected by the secondary interests of the institution in reducing costs and the secondary interests of the risk manager him or herself in professional reputation, job security, and advancement. In this individual focus, the ASHRM Code is not alone; official ethics statements for public risk managers take a similar stance. The Public Risk Management Association, the association of risk managers in the public sector, has a Code of Ethics (2014) that gives these illustrations of prohibited conflicts of interest: misuse of public resources, improper outside employment, acceptance of gifts or nepotism, and engagement in activities that will create a hostile work environment. Yet contemporary discussions of institutional conflicts of interest note that the analysis applied to conflicts in research and patient treatment may also be relevant to other aspects of the healthcare enterprise.

(Lo & Field 2009, p. 32)

Disclosure Programs and Institutional Conflicts of Interest

A recent, highly praised strategy for healthcare institutions to reduce costs of malpractice litigation is to encourage early settlement through disclosure, apology, and offer to patients. This strategy is proposed as a replacement for a “deny and defend” strategy seeking to win malpractice lawsuits. It has resulted in multiplicity of state laws shielding disclosures or apologies from litigation in a wide variety of ways. (Boothman et al. 2009) Important differences among such programs include whether they are disclosure only, whether they include apologies, and what kinds of disclosures are made. For example, some programs merely acknowledge to the patient that an adverse event occurred that was related to their care, without in any way apologizing or admitting responsibility for the event. Others will say they were sorry for what occurred but take care not to link such expressions of sympathy with admissions of fault that might give rise to liability claims.

The contemporary apology movement began with a report of “humanistic” risk management policies at a Veterans Affairs medical center that reported reduced liability payments. (Kramen & Hamm 1999) Although the study reported only a small case series and policy makers recognized that Veterans Affairs institutions might not be representative of healthcare institutions more generally, the reported findings generated great interest. In 2010, the Agency for Healthcare Research and Quality (AHRQ) funded a series of demonstration projects testing the concept that early disclosure or errors might reduce litigation costs (Mello, Studdert & Kachalia 2014). One larger hospital system with a disclosure program that also received grants under the AHRQ program—the University of Michigan—has reported reduced claims frequency, transaction costs, incidence of litigation, and time to dispute resolution. (Boothman et al. 2009) In addition, the Michigan experience reports a cultural shift to patient safety after inception of the disclosure program. (Boothman, Imhoff, & Campbell 2012)

Some published studies indicate reductions in litigation and settlement amounts after institution of a program of disclosure (Adams 2014). Other studies suggest that the changes are more likely to occur with cultural changes within institutions rather than being associated with state law innovations. (Perez & DiDona 2010) These studies report data that might suggest changes that are in both the interests of patients and the interests of institutions, if institutions shift to a culture of patient safety that results in reduced frequency of costly errors. On the other hand, reports of reduced costs may reflect reduced litigation costs and lower settlement offers to patients rather than concerns reflecting the interests of patients. The impact of institutional conflicts of interests thus remains unclear from these studies.

To consider the extent to which institutional conflicts of interest may have been recognized or acknowledged in studies of apology or disclosure programs, or in reports of the programs themselves, I conducted a pubmed search for “apology and malpractice and date after 2000.”¹ This search yielded a total of 42 articles. Many of these cited other articles discussing apology and disclosure programs and I included these as well in my database. After excluding all articles reporting activities outside of the United States and articles about which no information was available (primarily trade publications or local bar journals), I then reviewed 35 articles for the following factors: (1) did the article express a view about whether disclosure or apology was ethically desirable? (2) did the

¹ Other search strategies, such as “(apology or disclosure) and (malpractice or liability)” yielded thousands of articles, most dealing with malpractice risks.

article express a view about whether disclosure or apology was likely to create an improved climate of patient safety or otherwise improve care? (3) did the article express a view about whether apology or disclosure was likely to reduce the costs of litigation? (4) did the article raise any questions about whether the patient's interests were adequately represented in the process of settlement after apology or disclosure? Full results of my analysis are presented in the table in appendix A.

Some of the articles were discussions of the apology and disclosure movement presented as information to particular medical specialties (e.g. Vercler, Buchman & Chung 2014, plastic surgeons; Sohn & Bal 2012, orthopedists; Surbone 2012, oncologists; Baker, Lauro & Sintim-Damoa 2008, radiologists). Some articles focused on physician reluctance to disclosure and how this might be overcome (e.g. Surbone 2012; Pelt & Faldmo 2008; Saxton & Finkelstein 2008); Wei 2007). Many were articles in law reviews describing or assessing the impact of the different types of state apology and disclosure laws (e.g. Mello, Studdert & Kachalia 2014; Raper 2011; Hyman 2010; Mastroianni 2010; Perez & DiDona 2009; Robbinelt 2009; McDonnell & Guenther 2008). Three reported on the success of their institutional apology and disclosure programs (Boothman, Imhoff & Campbell 2012, University of Michigan; Quinn & Eichler 2008, Colorado COPIC program; Kraman et al. 2002, Lexington VA).

Ten articles raised questions about fair compensation for patients, several in ways that suggested sensitivity to the possibility of institutional conflicts of interest. Articles portraying the University of Michigan program, for example, cited cost reductions as only an incidental advantage of an effort to create an environment of fairness and openness (Boothman, Imhoff & Campbell 2012; Chung et al. 2011). Hyman (2010), cites data to the effect that patients report satisfaction with disclosure programs and do not report feeling pressured unfairly into settlements. Several articles point out that physicians may have fiduciary responsibilities to their patients that are not shared by risk managers (Loren et al. 2010; Quinn & Eichner 2008). Mello, Studdert & Kachalia (2014) note that compensation may be difficult to calculate fairly. Chung et al. (2011) caution against the possibility that physicians and hospitals that are independent actors (and not covered under a single self-insured malpractice umbrella) may behave strategically in order to shift liability costs to others involved in care.

Two articles stood out in raising questions about the possible impact of disclosure programs on fairness to patients. In a 2014 critical analysis of the impact of tort reform on liability costs, Mello, Studdert & Kachalia argue that tort reforms do not account for a significant percentage of the reduction in liability costs over the preceding decade. Instead, they argue that initial reports from the AHRQ demonstration projects suggest that programs communicating about injury with patients have had promising results. These authors note, however, that the proactive compensation component of these programs "may be more difficult for institutions to consistently execute" than communication, because insurers calculate compensation offers based on the likelihood of suit rather than on a principled analysis of whether substandard care caused harm. In their study of disclosure, apology, and offer programs, Bell and coauthors (Bell et al. 2010) conducted key informant interviews and found increased transparency, improved patient safety, reduced liability costs, and rapid and fair compensation as goals of these programs. Informants also feared that these programs would be perceived as "anti-consumer" efforts to settle cases quickly, for limited amounts, and without the benefit of

independent advice for patients. In the judgment of this study's authors, "Making whole those patients who have been harmed through medical negligence as quickly and fairly as possible after a harmful error diminishes any conflicts of interest on the part of the physician or the institution to help the patient while avoiding litigation and helps preserve therapeutic relationships between patients and caregivers." (Bell et al. 2010, 694-95)

Despite raising the issue of compensation fairness, none of these articles conceptualized the possibility of institutional conflict of interest directly. Importantly, none raised the possibility that risk managers might face this conflict in dealing with the disclosure process, making recommendations about settlement offers, or discussing compensation with patients.

Conclusion: Some Recommendations for Change

Despite their clear benefits, disclosure programs present possibilities of institutional conflicts of interest. They may encourage patients to settle claims of injury for settlement amounts that are unfair. Many discussions of these programs in the literature do not recognize these fairness concerns. Others, while recognizing the possibility of unfairness, do not conceptualize it in terms of a conflict of interest. In this conclusion, I suggest three additions to the disclosure process that might help to mitigate conflict of interest risks.

(1) *Reminding the patient that they have an opportunity to seek outside counsel and that doing so might be beneficial to them.* When attorneys representing clients consider entering into transactions with them, this is an attorney-client conflict of interest. In such cases, ethical rules require attorneys to tell their clients that they have an opportunity to seek outside counsel (ABA 2013). The institutional conflicts of interest faced by the risk manager or others representing the health care provider are similar in structure. Affording the opportunity for independent representation might thus be seen as an appropriate conflict-mitigation measure.

(2) *Reconsidering the confidentiality of settlement agreements.* When settlements are reached during the course of litigation, a condition of the settlement is typically that the settlement amount will be kept secret. This makes it difficult for patients and their representatives to know what others in similar circumstances may have received. It also makes it difficult for researchers to scrutinize the fairness of settlement patterns. (Knutsen 2010) Publication of settlement amounts in particular cases presents significant risks to patient privacy. It also risks misleading others, as publication of settlement amounts will not reveal the unique features of individual cases. On the other hand, publication of aggregate numbers such as how many settlements have been reached by the provider in a given year, in what categories of cases, and for what amounts, might increase transparency in a manner that supports public interests in improved care and fairness to patients.

(3) *Establishing a mechanism for impartial review of disclosure, apology, and offer programs.* In her review of the Jesse Gelsinger case, Wilson (2010) argues that banning institutional conflicts of interest would not have solved the problem of risks to patients that these pose. Instead, she argues for an ongoing external review of these conflicts, much as data safety monitoring boards assess the risks to patients of clinical trials on an ongoing basis. Along these lines, the University of Michigan disclosure, apology, and offer program features an internal review committee that assesses risk

manager determinations of whether the error in care was an unreasonable one before a settlement offer is made. This committee is designed to have a range of experts to counter the tendency to “protect ones own.” (Boothman et al. 2009) As it is an internal committee, however, it does not fully mitigate the risks of institutional conflicts.

Apology, disclosure and offer programs have growing appeal. Yet they present clear institutional conflicts of interest for risk managers. These conflicts have been under-appreciated in published assessments of these programs. Efforts to mitigate these conflicts should be further explored by risk managers.

References

- Adams, Megan A., B. Joseph Elmunzer & James M. Scheiman. 2014. “Effect of a Health System’s Medical Error Disclosure Program on Gastroenterology-Related Claims Rates and Costs.” *American Journal of Gastroenterology* 109: 460-464.
- American Bar Association (ABA). 2013. *Model Rules of Professional Conduct* 1.8(a)(2). http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_1_8_current_clients_specific_rules.html.
- American Society for Healthcare Risk Management (ASHRM). 2014. *Celebrating 30 Years, A Brief History of ASHRM: 1980-2010*. http://www.ashrm.org/ashrm/about/history/a_brief_history_of_ashrm/.
- , 2012. “Healthcare Risk Management Code of Professional Conduct.” http://www.ashrm.org/about/governance/files/Code_of_Conduct_2013.pdf
- , 2007. *Different Roles, Same Goal: Risk and Quality Management Partnering for Patient Safety*. http://www.ashrm.org/pubs/files/white_papers/Monograph.07RiskQuality.pdf.
- Baker, Stephen, Christine Lauro & Akosua Sintim-Damoa. 2008. “Malpractice Allegations and Apology Laws: Benefits and Risks for Radiologists.” *Journal of the American College of Radiology* 5(12): 1186-1190.
- Baily, Mary Ann, et al. 2006. *The Ethics of Using QI Methods to Improve Quality and Safety of Care*. Garrison, N.Y.: The Hastings Center.
- Bell, Sigall K. et al. 2012. “Disclosure, apology, and offer programs: stakeholders’ views of barriers to and strategies for broad implementation.” *Milbank Quarterly* 90(4): 682-705.
- Boothman, Richard C, Sarah J. Imhoff & Darrell A. Campbell, Jr. 2012. “Nurturing a culture of patient safety and achieving lower malpractice risk through disclosure: lessons learned and future directions.” *Frontiers of Health Services Management* 28(3): 13-28.
- Chung, Eugene, et al. 2011. “Malpractice Suits and Physician Apologies in Cancer Care.” *Journal of Oncological Practice* 7(6): 389-393.
- Core Risk Services. 2014. “History of health care risk management programs.” <http://www.coreriskservicesinc.com/history.php>.
- Dresser, Rebecca. 2008. “The Limits of Apology Laws.” *Hastings Center Report* 38(3): 6-7.
- Emanuel, Ezekiel J. & D. Steiner. 1995. “Institutional conflicts of interest.” *New England Journal of Medicine*: 332: 262-268.
- Foucar, E & M.R. Wick. 2007. “Tort reform: the pathologists’ perspective.” *Seminars in Diagnostic Pathology* 24(2): 131-47.

- Fredricks, Todd. R. 2012. "Efficacy of a Physician's Words of Empathy: An Overview of State Apology Laws." *Journal of the American Osteopathic Association* 112(7): 405-406.
- Friedman, Ralph S. & Ross McKinney, Jr. 2013. "Is Conflict of Interest Becoming a Challenge for Institution-Based Institutional Review Boards?" *Clinical Cancer Research* 19: 4034.
- Hyman, Chris Stern, et al. 2010. "Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?" *Journal of Health Politics, Policy and Law* 35(5): 797-828
- Ibsen, Henrik. 1882. "An Enemy of the People." Transl. R. Farquharson Sharp. Available as a Project Gutenberg EBook, <http://www.gutenberg.org/files/2446/2446-h/2446-h.htm>.
- Institute of Medicine (IOM). 1999. *To Err is Human: Building a Safer Health System*. Washington, D.C.: National Academies Press.
- Jennings, Bruce, et al., eds. 2007. *Health Care Quality Improvement: Ethical and Regulatory Issues*. Garrison, N.Y.: The Hastings Center.
- Kachalia, Allen & David W. Bates. 2014. "Disclosing medical errors: The view from the USA." *The Surgeon* 12: 64-67
- Kachalia, Allen & Michelle M. Mello. 2011. "New directions in medical liability reform." *New England Journal of Medicine* 364(16): 1564-1572.
- Knutsen, Erik. 2010. "Keeping Settlements Secret." *Florida State University Law Review* 37(Summer): 945-979.
- Kramen, S.S. et al. 2002. "John M Eisenberg Patient Safety Awards Advocacy: The Lexington Veterans Affairs Medical Center." *Joint Commission Journal of Quality Improvement* 28(12): 646-670.
- Kramen, SS & G Hamm. 1999. "Risk management: extreme honesty may be the best policy." *Annals of Internal Medicine* 131(12) 963-67.
- Leape, Lucian L. 1994. "Error in Medicine." *Journal of the American Medical Association* 272:1851-1857.
- Lo, Bernard & Marilyn J. Field, eds. 2009. *Conflict of Interest in Medical Research, Education, and Practice*. Washington, D.C.: Institute of Medicine.
- Loren, D.J. et al. 2010. "Risk managers, physicians, and disclosure of harmful medical errors." *Joint Commission Journal of Quality & Patient Safety* 36(3): 101-108.
- Mastroianni, Anna C., et al. 2010. "The Flaws in State 'Apology' And 'Disclosure' Laws Dilute Their Intended Impact On Malpractice Suits." *Health Affairs* 29(9): 1611-1619.
- McDonnell, William M. & Elisabeth Guenther. 2008. "Narrative Review: Do State Laws Make it Easier to Say 'I'm Sorry?'" *Annals of Internal Medicine* 149(11): 811-815.
- Mello, Michelle M., David M. Studdert & Allen Kachalia. 2014. "The Medical Liability Climate and Prospects for Reform." *Journal of the American Medical Association* (Oct. 30), doi:10.1001/jama.2014.10705.
- Murtagh, Lindsey et al. "Disclosure-and-resolution programs that include generous compensation offers may prompt a complex patient response." *Health Affairs* 31(12): 2681-2689.

- Pelt, Jenny L. & Lynda P. Faldmo. 2008. "Physician Error and Disclosure." *Clinical Obstetrics & Gynecology* 51(4): 700–708.
- Perez, Bianca, and Toni DiDona. 2009. "Assessing Legislative Potential to Institute Error Transparency: A State Comparison of Malpractice Claims Rates." *Journal for Healthcare Quality* 32(3): 36-41.
- Petronio, Sandra, et al. 2013 "Disclosing Medical Mistakes: A Communication Management Plan for Physicians." *The Permanente Journal* 17(2): 73-79.
- Public Risk Management Association. 2014. Code of Ethics.
<http://www.primacentral.org/resources/codeofethics.pdf>.
- Quinn, Richert E & Mary C. Eichler. 2008. "The 3Rs Program: The Colorado Experience." *Clinical Obstetrics and Gynecology* 51(4): 709-718.
- Raper, Steven E. 2011. "No Role for Apology: Remedial Work and the Problem of Medical Injury." *Yale Journal of Health Policy, Law & Ethics* 11: 267-327.
- Regis, C. & J. Poitras. 2010. "Healthcare mediation and the need for apologies." *Health Law Journal* 18:31-49.
- Robbennelt, Jennifer. 2009. "Apologies and Medical Error." *Clinical Orthopedics and Related Research* 467(2): 376–382.
- Rose, Susannah L. 2013. "Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness." *Journal of Law, Medicine & Ethics* 41(3): 680-687.
- Saitta, Nicole & Samuel D. Hodge, Jr. 2012. "Efficacy of a Physician's Words of Empathy: An Overview of State Apology Laws." *Journal of the American Osteopathic Association* 112(5): 302-306.
- Saxton, J.W. & M.M. Finkelstein. 2008. "Adverse event management: your evidence to decrease professional liability risk. *Journal of Medical Practice Management* 24(1): 5-8.
- Shafer, Arthur. 2004. "Biomedical conflicts of interest: a defense of the sequestration thesis—learning from the cases of Nancy Olivieri and David Healy." *Journal of Medical Ethics* 30: 8-24.
- Sohn, David H. & B. Sonny Bal. 2012. "Medical Malpractice Reform: The Role of Alternative Dispute Resolution." *Clinical Orthopaedics and Related Research* 470(5):1370-1378
- Stanford University. 2014. "Rule 4.7. Institutional Conflict of Interest in Research Involving Human Subjects." <http://doresearch.stanford.edu/policies/research-policy-handbook/conflicts-commitment-and-interest/institutional-conflict-interest-research-involving-human-subjects#anchor-670>.
- Surbone, A. 2012. "Oncologists' difficulties in facing and disclosing medical errors: suggestions for the clinic." *American Society of Clinical Oncology Education Book* 2012: e24-27, doi: 10.14694/EdBook_AM.2012.32.e24.
- Taft, Lee. 2005. "Apology and medical mistake: opportunity or foil? *Annals of Health Law* 14: 55-94.
- Thompson, Dennis. 1993. "Understanding Financial Conflicts of Interest." *New England Journal of Medicine* 329: 573-576.
- Vercler, C.J., S.R. Buchman, & K.C. Chung. 2014. "Discussing Harm-Causing Errors With Patients: An Ethical Primer for Plastic Surgeons." *Annals of Plastic Surgery* (May 14, Epub ahead of print, PMID: 24830658).

- Wei, M. 2007. "Doctors, apologies, and the law: an analysis and critique of apology laws." *Journal of Health Law* 40(1):107-159.
- Wilson, Robin Fretwell. 2010. "The Death of Jesse Gelsinger: New Evidence of the Influence of Money and Prestige in Human Research." *American Journal of Law & Medicine* 36(2-3): 295-325.
- Zimmerman, R. 2004. "Doctors' new tool to fight lawsuits: saying 'I'm sorry.'" *Journal of the Oklahoma State Medical Association* 97(6): 245-47.

Appendix A

Table of Articles Surveyed

Study	Date	Disclosure Ethical?	Quality Improvement?	Reduced Costs?	Institutional Conflict?	Notes
Mello, Studdert & Kachalia	2014	Y*	Y	Y	Article notes that compensation associated with disclosure may be difficult for insurers used to assessing compensation by the likelihood of litigation	Discussion of reforms and effect on liability claims
Vercler, Buchman & Chung	2014	Y	Y	Y		
Kachalia & Bates	2014	Y	Y	Y		
Petronio	2013	Y				
Bell et al.	2012	Y	Y	Y	Y	
Murtagh et al.	2012			Y (arguing more patients might sue and costs rise)		
Fredricks	2012	Y				
Saitta & Hodge	2012	Y		Y		
Surbone	2012	Y				
Sohn & Bal	2012			Y		
Boothman, Imhoff & Campbell	2012	Y	Y	Y	Goal of Michigan program to compensate patients quickly and fairly;	

					recognizes the difficulties in valuing claims economically. States that one way to value claims would be what they might bring in litigation; failing to heed this might lead patients to think they are being made cheap offers and treated unfairly.	
Raper	2011	Y	Y			
Kachalia & Mello	2011		Y	Y		Analysis of tort reforms
Conway et al.	2011					
Chung et al.	2011	Y	Y	Y	Describes Michigan program as creating environment of fairness and openness; cost savings an incidental advantage	Notes that the Michigan approach may not work in systems that don't self insure their physicians under an umbrella, because of the possibility of strategic behavior to shift costs
Hyman	2010		Y		No, but does consider whether patients felt pushed into settlements and whether they reported satisfaction with the process	

Mastroianni	2010	Y		Y (arguing that state apology laws are inadequate to reduce provider fears of litigation; suggests adopting "best practices" for disclosures)		
Perez & DiDona	2009		Y (arguing that there is no significant difference in paid malpractice claims between states with and states without disclosure or apology laws)	Y		
Loren et al.	2010	Y			Compares fiduciary role of physicians to risk manager role in protecting institution from financial harm	
Regis & Poitras	2010	Y		Y		
Robbinnelt	2009	Y		Y		
Boothman et al.	2009					
McDonnell & Guenther	2008	Y	Y	Y	Citations to the possibility that patients may receive inadequate compensation	
Baker, Lauro & Sintim-Damoa	2008	Y	Y	Y (also noting that disclosure may increase risks to radiologists, given their		

				separation from patients)		
Quinn & Eichler	2008	Y	Y	Y	Reports importance of bearing in mind fiduciary responsibilities to patients	
Pelt & Faldmo	2008	Y		Y		
Saxton & Finkelstein	2008			Y		
Dresser	2008				Overview of the limits of apology laws; mentions the need for patient compensation	
Foucar & Wick	2007			General overview of tort reform		
Wei	2007	Discussion of barriers to apologies and how to overcome them				
Wagner	2006	Y				
Taft	2005	Y (healing power of apology)	Y	Y	Discusses how liability shields for expressions of sympathy but not for admissions of wrongdoing corrupt the moral power of apology.	
Zimmerman	2004			Y		
Kraman et al.	2002	Y	Y	Y		

*Y means only that the issue is raised in the article. It does not signify the position taken in the article about the issue.